

EXHIBIT RR

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

ARBUTUS BIOPHARMA CORPORATION
and GENEVANT SCIENCES GmbH,

Plaintiffs,

v.

MODERNA, INC. and MODERNATX, INC.,

Defendants.

MODERNA, INC. and MODERNATX, INC.,

Counterclaim-Plaintiffs,

v.

ARBUTUS BIOPHARMA CORPORATION
and GENEVANT SCIENCES GmbH,

Counterclaim-Defendants.

C.A. No. 22-252-MSG

**CONTAINS INFORMATION
DESIGNATED HIGHLY
CONFIDENTIAL – OUTSIDE
COUNSEL EYES ONLY BY THE
PARTIES**

SUR-REPLY REPORT OF ROBERT PRUD'HOMME, PHD

Dated: April 9, 2025



chromatographic peaks shown in ¶47, the straight line that is chosen to represent the “floor” of the integration does not correspond to the experimental baseline that is below that line. Nothing in Dr. Schuster’s explanation changes my opinion that Coriolis’ approach to peak integration is prone to skewing the data. I continue to agree with Dr. Fenton’s criticisms of Dr. Schuster’s use of manual integration and the results presented. *See, e.g.*, Fenton Rebuttal Report VII.D.

12. Dr. Schuster further opines on reply that “it is likely that many, if not substantially all of the [REDACTED] were separated out into the top fractions.” Schuster Reply ¶71. But Dr. Schuster improperly assumes that the [REDACTED] That is not the case. As I noted in my Rebuttal Report (*e.g.*, ¶412), other lipid species, like cholesterol crystals as just one example, can also form in these LNP compositions. These cholesterol crystals would be more dense than a standard LNP and would not move to the top fractions, as Dr. Schuster alleges. In fact, these cholesterol forms would be expected to be more prevalent in the lower fractions, leading to a pattern of increasing cholesterol mol% with increasing fraction, which is precisely what can be observed in Dr. Schuster’s lipid content results.

13. Finally, Dr. Schuster presents new testing in his reply report in an effort to demonstrate that “the sample preparation and UC methodology described in [his] Opening Report do not cause particle change or disruption.” Schuster Reply ¶110. I disagree that such a conclusion can be drawn from this very limited testing.

14. First, the use of DLS and NTA alone is not sufficient to show that the LNPs in the composition are not changing post-processing, particularly not changing in lipid content. For example, neither of these techniques provides any information on any chemical degradation that might be occurring. Specifically, the handling and/or processing of the LNPs, especially the centrifugation of expired product that has been handled and undergone centrifugation for hours at

room temperature, may cause degradation of species in the LNP. These changes would not be captured by the techniques used by Dr. Schuster in the new testing he and his colleagues performed on reply and therefore this testing cannot be used to determine whether the processing applied to the LNPs has had any effect on the composition of the individual LNPs in the formulation. Rather, Dr. Schuster should have at least repeated the lipid content testing, similar to that which had been reported in his Opening Report.

15. Second, Dr. Schuster performed this limited testing on a single sample. A sample size of one (let alone an expired sample) is not sufficient to be able to draw any broad conclusion about the effect of the handling and/or processing steps applied by Dr. Schuster and his colleagues on the LNPs in Moderna's COVID-19 vaccine.

16. Third, I find the data obtained by Dr. Schuster surprising at best. For example, he reports a 0.0% difference between the two very broad PDI measurements (PDI= 0.22) and only 1.08 nm differences in LNP sizes (135.19 nm native sample and 134.11 nm UC sample). This broad PDI with this reported precision between two measured LNP diameters that have been handled so differently is highly implausible. At best, I can surmise this could be due to the DLS instrument analysis program providing an improper deconvolution of the correlation function because of the truncation of the correlation function at longer times. This can occur when large polydispersities like this are measured for samples having large species. Dr. Schuster did not filter the LNP sample before analysis, whereas Moderna specifies [REDACTED]. See, e.g., Schuster Reply ¶76. There is no dispute that Moderna has reported the presence of [REDACTED] particles in its COVID-19 vaccine, see, e.g., MRNA-GEN-00177803; Schuster Reply ¶76, but Dr. Schuster has not attempted to quantify the amount or concentration of these particles in the samples he was testing.

17. Therefore, Dr. Schuster's additional testing does not change my opinions with respect to the effect of Coriolis' handling and processing on the LNPs in Moderna's COVID-19 vaccine.